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10/019,402	12/28/2001	Hitoshi Matsumoto	VX012397 PCT	3876

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[REDACTED] EXAMINER

JAGOE, DONNA A

ART UNIT	PAPER NUMBER
1614	10

DATE MAILED: 04/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/019,402	MATSUMOTO ET AL.
Examiner	Art Unit	
Donna A. Jagoe	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on _____.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-14 and 18-25 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-14 and 18-25 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ .
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>5,6</u> .	6) <input type="checkbox"/> Other: _____

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of group I, claims 1-7, 13-14 and 18-25 in Paper No. 9 is acknowledged. The traversal is on the ground(s) that Rule 13 permits the inclusion of an independent claim for a given product, and independent claim for a process especially adapted for the manufacture of the product and an independent claim for use of the product. This argument is found persuasive.

The examiner acknowledges the election of juice as the elected species. It should be remembered that the purpose of an election of species requirement is to simplify the search and issues considered during prosecution, and that because this is so, the ultimate allowance of a generic claim will encompass all additional species within the scope of the allowed genus. Stated alternatively, the purpose of an election of species requirement, as opposed to a restriction between claim groups, is to reduce the burden on the examiner during prosecution only; a full search is merely postponed until allowance of the generic claim.

Claims 1-14 and 18-25 are presented for examination.

Claims present in the instant application.

Applicant asserts that there is a claim 26 present in the instant application. The following claims are currently present in the instant application:

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Claim 1: (original) A black currant anthocyanin-containing composition for food wherein the composition comprises 1 to 25% by weight, preferably 5 to 25% by weight of black currant anthocyanin, on the basis of solid matters.

Claim 2 (original) The black currant anthocyanin-containing composition for food according to claim 1 wherein the composition comprises 5 to 25% by weight of the black currant anthocyanin on the basis of solid matters.

Claim 3 (amended) The black currant anthocyanin-containing composition for food according to claim 1 wherein the black currant anthocyanin is prepared by purifying and concentrating black currant juice with a charged reverse osmosis membrane.

Claim 4 (amended) The black currant anthocyanin-containing composition for food according to claim 1 wherein the black currant anthocyanin comprises delphinidin with delphinidin content being 0.5 to 12.5% by weight, preferably 2.5 to 12.5% by weight, on the basis of solid matters.

Claim 5 (original) The black currant anthocyanin-containing composition for food according to claim 4 wherein the delphinidin content is 2.5 to 12.5% by weight on the basis of solid matters.

Claim 6 (amended) The black currant anthocyanin-containing composition for food according to claim 1 wherein the black currant anthocyanin comprises delphinidin-3-o-rutinoside with the delphinidin-3-o-rutinoside content being 0.4 to 10% by weight, preferably 2 to 10% by weight, on the basis of solid matters.

Claim 7 (original) The black currant anthocyanin-containing composition for food according to claim 6 wherein the delphinidin-3-o-rutinoside content is 2 to 10% by weight on the basis of solid matters.

Claim 8 (original) A process for producing black currant anthocyanin-containing compositions for food wherein black currant juice, as a starting material, is purified and concentrated with a charged reverse osmosis membrane.

Claim 9 (original) The process for producing black currant anthocyanin-containing compositions for food according to claim 8 wherein the charged reverse osmosis membrane is a negatively charged reverse osmosis membrane.

Claim 10 (original) The process for producing a black currant anthocyanin-containing composition for food according to claim 9 wherein the negatively charged reverse osmosis membrane has salt retention rate of 5 to 20% in the case of NaCl.

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Claim 11 (original) A process for producing a black currant anthocyanin-containing composition for food wherein black currant juice, as a starting material, is purified and concentrated with a charged reverse osmosis membrane and an ion-exchange resin.

Claim 12 (original) The process for producing black currant anthocyanin-containing compositions for food according to claim 11 wherein the ion-exchange resin is a strong acid cation-exchange resin.

Claim 13 (amended) A functional food or drink which comprises the composition for food according to claim 1.

Claim 14 (original) The functional food or drink according to claim 13 wherein the food or drink is candy, chewing gum, juice, chocolate, tablet, gelatinous food or jam.

Claim 15 is cancelled

Claim 16 is cancelled

Claim 17 is cancelled

Claim 18 (added with amendment dated 4-11-02) The black currant anthocyanin-containing composition for food according to claim 2 wherein the black currant anthocyanin is prepared by purifying and concentrating black currant juice with a charged reverse osmosis membrane.

Claim 19 (added with amendment dated 4-11-02 and amended 9-26-02) The black currant anthocyanin-containing composition for food according to claim 2 wherein the black currant anthocyanin comprises delphinidin with delphinidin content being 0.5 to 12.5% by weight, preferably 2.5 to 12.5%, on the basis of solid matters.

Claim 20 (added with amendment dated 4-11-02) The black currant anthocyanin-containing composition for food according to claim 3 wherein the black currant anthocyanin comprises delphinidin with delphinidin content being 0.5 to 12.5% by weight, preferably 2.5% to 12.5% by weight, on the basis of solid matters.

Claim 21 (added with amendment dated 4-11-02) The black currant anthocyanin-containing composition for food according to claim 2 wherein the black currant anthocyanin comprises delphinidin-3-o-rutinoside with the delphinidin-3-o-rutinoside content being 0.4 to 10% by weight, preferably 2 to 10% by weight, on the basis of solid matters.

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Claim 22 (originally claim 23 and renumb red under rule 1.126¹ as claim 22, added with amendment dated 4-11-02) The black currant anthocyanin-containing composition for food according to claim 3 wherein the black currant anthocyanin comprises delphinidin-3-o-rutinoside with the delphinidin-3-o-rutinoside content being 0.4 to 10% by weight, preferably 2 to 10% by weight, on the basis of solid matters.

Claim 23 (added with the amendment dated 9-26-02) The black currant anthocyanin-containing composition for food according to claim 3 wherein the black currant anthocyanin comprises delphinidin-3-o-rutinoside with the delphinidin-3-o-rutinoside content being 0.4 to 10% by weight, preferably 2 to 10% by weight, on the basis of solid matters.

Claim 24 (added with the amendment dated 9-26-02, renumbered under rule 1.126) The composition for food according to claim 1, which has at least one effect for improving visual function selected from effects (1) to (8) as follows:

- (1) an effect of alleviating asthenopia;
- (2) an effect of lowered visual acuity;
- (3) an effect of alleviating myopia;
- (4) an effect of lowering refraction power of crystalline lens;
- (5) an effect of visual acuity in the darkness;
- (6) an effect of improving adaptation to darkness;
- (7) an effect of improving retinal function; and
- (8) an effect of improving rental rod.

Claim 25 (added with the amendment dated 9-26-02, renumbered under rule 1.126) The functional food or drink according to claim 13, which has at least one effect for improving visual function selected from effects (1) to (8) as follows:

- (1) an effect of alleviating asthenopia;
- (2) an effect of lowered visual acuity;
- (3) an effect of alleviating myopia;
- (4) an effect of lowering refraction power of crystalline lens;
- (5) an effect of visual acuity in the darkness;
- (6) an effect of improving adaptation to darkness;
- (7) an effect of improving retinal function; and
- (8) an effect of improving rental rod.

¹ § 1.126 Numbering of claims.

The original numbering of the claims must be preserved throughout the prosecution. When claims are canceled the remaining claims must not be renumbered. When claims are added, they must be numbered by the applicant consecutively beginning with the number next following the highest numbered claim previously presented (whether entered or not). When the application is ready for allowance, the examiner, if necessary, will renumber the claims consecutively in the order in which they appear or in such order as

Claim Objections

Applicant is advised that should claim 22 be found allowable, claim 23 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claims 24 and 25 are objected to because of the following informalities: line 11 of the claims recites an effect of improving "rental rod". It is not understood what is meant by "rental rod". It appears to be a typographical error. In the interest of advancing prosecution of the case, the claims are being interpreted as **retinal rod**. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7, 13-14 and 18-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

may have been requested by applicant.

1. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949).

In the present instance:

- A. Claim 1 recites the broad recitation 1 to 25% by weight, and the claim also recites 5 to 25%, which is the narrower statement of the range/limitation.
- B. Claim 4 recites the broad recitation 0.5 to 12.5%, and the claim also recites 2.5 to 12.5%, which is the narrower statement of the range/limitation.
- C. Claim 6 recites the broad recitation 0.4 to 10%, and the claim also recites 2 to 10%, which is the narrower statement of the range/limitation.
- D. Claim 19 recites the broad recitation 0.5 to 12.5%, and the claim also recites 2.5 to 12.5%, which is the narrower statement of the range/limitation.

E. Claim 20 recites the broad recitation 0.5 to 12.5%, and the claim also recites 2.5 to 12.5%, which is the narrower statement of the range/limitation.

F. Claim 21 recites the broad recitation 0.4 to 10%, and the claim also recites 2 to 10%, which is the narrower statement of the range/limitation.

G. Claim 22 recites the broad recitation 0.4 to 10%, and the claim also recites 2 to 10%, which is the narrower statement of the range/limitation.

H. Claim 23 recites the broad recitation 0.4 to 10%, and the claim also recites 2 to 10%, which is the narrower statement of the range/limitation.

2. The term "functional" in claims 13, 14 and 25 is a relative term, which renders the claim indefinite. The term "functional" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Since no guidance is provided as to how "non-functional" a given value can be and still fall within the scope of the instantly claimed subject matter as circumscribed by the term "functional" the metes and bounds of the term are not clear, making it impossible to ascertain with reasonable precision when that term is infringed and when it is not.

The remaining claims are indefinite to the extent that they read on the rejected base claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. Claims 8-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lawhon et al. US. Patent No. 4,643,902.

The claims are drawn to a process for producing black currant anthocyanin-containing compositions for food wherein the black currant juice is purified and concentrated with a (negatively) charged reverse osmosis membrane and optionally an ion-exchange resin.

Lawhon et al. teach a method of producing sterile and concentrated juices with improved flavor and reduced acid. The reference teaches treatment of the filtered juice by reverse osmosis (RO) to concentrate the flavor and aroma components in the RO retentate. The concentrated flavor and aroma components can then be recombined with the UF retentate to provide a juice suitable for storage or removed in the concentrated form for later dilution before use. The acid content of the juice can be reduced by passing a portion of the RO retentate through an ion-exchange column (column 3, lines 15-30). The process is broadly applicable to food juices such as currants (column 3, lines 50-66).

It differs in that it teaches currants. The instant application teaches black currants.

The process of the instant application is drawn to the process of producing the juice. It is *prima facie* obvious to substitute equivalents, motivated by the reasonable expectation that the respective species will behave in a comparable manner or give comparable results in comparable circumstances. *In re Ruff* 118 USPQ 343; *In re Jezel* 158 USPQ 99; the express suggestion to substitute one equivalent for another need not be present to render the substitution obvious. *In re Font*, 213 USPQ 532. Since the process is applicable to currants one of ordinary skill in the art would have been

motivated to employ the method of extracting the juice from black currants by reverse osmosis and/or ion-exchange resin since Lawhon et al. teach it to be useful to produce juice from currants.

2. Claim1-7, 13-14 and 18-25 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Lawhon et al. U.S. 4,643,902 (A) in view of Nakhmedov et al. (Konservnaya I Ovoshchesushil'naya Promyshlennost (U) and Laboratoires Chibret, Societe Anonyme, GB 1,007,751 (N).

The claims are drawn to a composition comprising a black currant anthocyanin-containing composition wherein the composition comprises 1 to 25% solids with dependent claims drawn to 0.4 to 10% delphinidin-3-o-rutinoside content, purified and concentrated by reverse osmosis and optionally ion exchange resin.

Lawhon et al. teach purifying and concentrating juice such as currant juice through by reverse osmosis and optionally by ion exchange resin. It does not teach black currants. It would have been obvious to substitute black currant juice instead of currant juice since Lawhon et al. teach the reverse osmosis and ion-exchange to be employed for currant juice. It is *prima facie* obvious to substitute equivalents motivated by the reasonable expectation that the respective species will behave in a comparable manner or give comparable results in comparable circumstances. *In re Ruff* 118 USPQ 343; *In re Jeze* 158 USPQ 99; the express suggestion to substitute one equivalent for another need not be present to render the substitution obvious. *In re Font*, 213 USPQ 532. Since the process is applicable to currants one of ordinary skill in the art would

have been motivated to employ the method of extracting the juice from black currants by reverse osmosis and/or ion-exchange resin since Lawhon et al. teach it to be useful to produce juice from currants.

Lawhon et al. does not teach the percent solids in the black currant material for food. Nakhmedov et al. teach that wastes from black currant contained 5 to 10% solids, which is encompassed by the instantly claimed 1 to 25% or 5 to 25%. Regarding the delphinidin-3-o-rutinoside, it is known that delphinidin 3-rutinoside is contained in the anthocyanin of black currant fruit as recited by Nakhmedov et al. (see abstract).

Regarding claims 24 and 25, drawn to the composition for treatment of various vision problems, the intended use of the claimed composition does not patentably distinguish the composition, *per se*, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting.

"The patentability of a product does not depend upon its method of production. If the product in a product-by-process claim is the same as or obvious from a product of the prior art, then the claim is unpatentable even though the prior art product was made by a different process." *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted). Once the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to the applicant to come forward with evidence

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establishing an unobvious difference between the claimed product and the prior art product. *In re Marosi*, 218 USPQ 289, 292 (Fed. Cir. 1983).

Laboratoires Chibret Societe Anonyme teach that anthocyanin glucosides such as those obtained from bilberries are useful for visual acuity enhancing night vision (column 1, lines 20-25). It would have been obvious to employ black currant anthocyanin for vision problems such as visual acuity and night vision. Motivation to employ black currants would come from the knowledge that Laboratoires Chibret Societe Anonyme teach anthocyanins such as those obtained from bilberries to be useful for such a purpose. It is *prima facie* obvious to substitute equivalents, motivated by the reasonable expectation that the respective species will behave in a comparable manner or give comparable results in comparable circumstances. *In re Ruff* 118 USPQ 343; *In re Jezel* 158 USPQ 99; the express suggestion to substitute one equivalent for another need not be present to render the substitution obvious. *In re Font*, 213 USPQ 532. Since both bilberries and black currants contain anthocyanin, it would have been obvious to employ black currants to improve vision since Laboratoires Chibret Societe Anonyme teach anthocyanin containing vegetable extracts of fruit juices to be useful for such a purpose.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna A. Jagoe whose telephone number is (703) 306-5826. The examiner can normally be reached on 8:00 A.M. - 4:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725.. The fax phone

numbers for the organization where this application or proceeding is assigned are (703) 305-3230 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Donna Jagoe
Patent Examiner
Art Unit 1614

April 5, 2003